K123161

MAR 1 4 2013

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This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 C.F.R. 807.92.

General Information

A.	Submitted By:	Dr. David L. Spainhower, DDS SmartGuard, Inc. 2360 Corporate Circle, Suite 400 Henderson, NV 89074
	Contact Person:	Dr. David L. Spainhower
	Date Prepared:	August 24, 2012
B.	Device Trade Name:	SmartGuard® Night Guard, SmartGuard® Original, SmartGuard® Night Guard Original and SmartGuard Elite™
	Common Name:	Dental Guard/Night Guard/Mouth Guard
	Classification Name:	Unclassified
C.	Predicate Devices: (SleepRight -	SleepRight Products (K071404 and K022809) Select; SleepRight – Low Profile; SleepRight – Advance; SleepRight – Low Profile Rx, Advance Rx) NTI Tension Suppression System (K010876 & K981546) Freeway Comfort Bite Guard (K110468) GrindGuardn (K082723) Brux-TMD QuickSplint (K111066) Doctor's Night Guard (K073220)

D. Device Description:

SmartGuard® The SmartGuard® is a dental night guard composed of Elvax and once this thermoplastic material is submerged in hot water (see molding instructions) it softens and conforms to the individual's anterior maxillary teeth from first bicuspid to first bicuspid. SmartGuard® is designed to be worn on the anterior, upper 6 to 8 teeth, preventing the posterior teeth from coming into occlusion, which relaxes the jaw muscles and helps to reduce jaw clenching and grinding and reduces the associated symptoms. The lower bottom anterior teeth bite against the bottom of the substrate with the ability to slide around freely as the device reduces posterior teeth cuspal interferences. The design features of SmartGuard® allow patients to easily mold this device at home or in a prescribing office, to fit their teeth properly. The SmartGuard® is designed to be worn at night and not longer than 12 consecutive hours in a 24 hour period.

SmartGuard® Original and SmartGuard Elite® differ slightly in design, with the primary difference being in the width of the palatal ex-tension, (Original 21mm and Elite 30 mm) as well as the distance between the outer rim and mesial/occlusal surface of the palatal extension (Original 10 mm and Elite 9 mm).The SmartGuard Elite® was designed to fit the majority of individuals mouths. However, if the patient has a small mouth or has a sensitive gag reflex, the SmartGuard® Original might be a better fit.

OTC:

- Protection against bruxism or night time teeth grinding
- Intended to reduce damage to the teeth and reduce noise associated with bruxing and/or grinding.

Rx:

- Protection of teeth grinding, bruxism, and jaw clenching.
- Protection of restoration from injury due to bruxism or clenching.
- Relief of bruxism related headaches and pains.
- Short-term pain relief from muscle spasm due to occlusal interference; for the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscles.
- Temporary treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains.

E. Comparison of Technical Characteristics of Predicate Devices

See Attachment Comparison of predicate devices

OTC:

The SmartGuard® devices are substantially equivalent to the SleepRight Select, SleepRight Low Profile, SleepRight Advance (cleared under K071404) and Freeway Comfort Bite Guard (K110468) with product code OBR. SmartGuard® is substantially equivalent to the above indicated devices cleared under the referenced 510K numbers. SmartGuard® is identical in design and material to the OTC devices cleared under K071404 and K110468. It has the same intended uses, indications, and similar technological characteristics as its predicate devices. The minor technological differences between SmartGuard® and the predicate devices raise no new questions of safety or effectiveness. Thus, SmartGuard® is substantially equivalent to the above referenced products and product code **OBR** noted above.

Rx:

The SmartGuard® devices are also substantially equivalent to SleepRight Low Profile Rx, SleepRight Advance Rx, Freeway Comfort Bite Guard, GrindGuardn and Brux-TMD QuickSplint with product code MQC. SmartGuard® has the same intended uses, indications and similar technological characteristics as its predicate devices. The minor technological differences between SmartGuard® and the predicate devices raise no new questions of safety or effectiveness. Thus, SmartGuard® is substantially equivalent to the above referenced products with the Product Code **MQC.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

SmartGuard, Incorporated
C/O Ms. Shelly Garg
Attorney
Humphrey & Associates, P.A.
601 Brickell Key Drive, Suite 104
MIAMI FL 33131

Re: K123161
Trade/Device Name: SmartGuard® Night Guard, SmartGuard® Original, SmartGuard® Night Guard Original and SmartGuard Elite™
Regulation Number: Unclassified
Regulation Name: Prescription Mouthguard
Regulatory Class: Unclassified
Product Code: MQC, OBR
Dated: January 10, 2013
Received: February 12, 2013

Dear Ms. Garg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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October 1, 2012

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: SmartGuard® Night Guard, SmartGuard® Original, SmartGuard® Night Guard Original and SmartGuard Elite™

Indications For Use:

OTC:

- Protection against bruxism or night time teeth grinding
- Reduce damage to the teeth and reduce the noise associated with bruxing and/or grinding

Rx:

- Protection of teeth grinding, bruxism, and jaw clenching.
- Protection of restorations from injury due to bruxism or clenching.
- Relief of bruxism related headaches and pains.
- Short-term pain relief from muscle spasm due to occlusal interference; for the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.
- Temporary treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains.

Prescription Use __X_____ AND/OR Over-The-Counter Use ___X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
.nfection Control, Dental Devices

510(k) Number: k123161